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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p>09/716,639</p>	<p>Applicant(s)</p> <p>COLAVIZZA ET AL.</p>	
	<p>Examiner</p> <p>David A. Lambertson</p>	<p>Art Unit</p> <p>1636</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-22 and 25-63 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed September 3, 2003. Amendments were made to the claims. Specifically, claims 1-19, 23 and 24 were cancelled and new claims 26-53 were added.

Claims 20-22 and 25-53 are pending in the instant application. Claims 20-22 and 25 are withdrawn from consideration as being drawn to a non-elected invention. Claims 26-53 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 29, 2002, that is not addressed in this action has been withdrawn.

### ***Specification***

The substitute specification provided in the response filed September 3, 2003 is acknowledged and entered.

### ***Claim Objections***

Claim 27 is objected to because of the following informalities: The claim contains the word "doughis;" it appears that this is a misspelling of the words "dough" and "is." Appropriate correction is required.

Claims 27-30, 33, 36-39 and 41-43 are objected to because of the following informalities: the repeated indication of the deposit address is unnecessary and cumbersome, making it difficult to understand the limitations of the claims. It is clear from the deposit number and the indication of the deposit address in the specification where the particularly claimed strains are deposited,

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and it is clear from the specification that the strains were deposited under the Budapest Treaty. Therefore it is unnecessary to indicate the address and the deposit treaty in any claim, let alone every claim. Appropriate correction is required.

New Grounds for Rejection

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-40 and 47-53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims are directed to a baker's yeast strain that could be present in nature. It would be remedial to indicate that the strain was "isolated" or "recombinant" (i.e., "An isolated/recombinant baker's yeast..."). **This is a new rejection that is necessitated by amendment.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-30, 32-37 and 47-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the CNCM I-2421 yeast strain, CNCM I-2422 yeast strain and yeast strain having a complete deletion of the *PADI* gene, does not reasonably provide enablement for any yeast strain having "good general performance in bread-making processes,"

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being “resistant to stress caused by freezing,” and not having the effect of producing “bad taste or off-flavors.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection that is necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

**Nature of the invention.** The nature of the invention is any baker’s yeast strain, wherein the strain has the properties of having a “good general performance in bread-making processes,” being “resistant to stress caused by freezing,” and not having the effect of producing “bad taste or off-flavors.” Notwithstanding the indefinite nature of two of these three characteristics (see the Maintained Rejections under 35 USC § 112, second paragraph), the claim is directed to a great number of baker’s yeast for which there is no clear structure-function relationship as it regards the characteristics of the claimed yeast. Without such knowledge, the skilled artisan would be unable to make the claimed yeast because the skilled artisan would not know what genetic alterations (aside from the complete deletion of *PADI*) would result in the claimed yeast

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strain. It is noted that the *identification* of a yeast strain that fits the desired characteristics (whatever they may be) does not equate to the ability to *make* the yeast strain.

**Scope of the invention.** The scope of the invention is very broad, encompassing a great number of yeast that may or may not have been made, and that may also fit the limitations of the claim. In specific embodiments, the claims recite a limitation where it appears the yeast strains are the CNCM I-2421 and CNCM I-2422 strains, and where the yeast strain is a strain that harbors a complete deletion of the *PAD1* gene. These strains are clearly enabled within the scope of the invention because the skilled artisan would be able to obtain a sample of the deposited yeast strains by official request, and the skilled artisan would be well aware of the proper genetic manipulations required in order to make a strain deleted for the *PAD1* gene. However, beyond this scope, the skilled artisan would not be able to make the claimed yeast strains because the skilled artisan cannot be apprised of what other genetic manipulations would result in the desired characteristics. Furthermore, a test to identify a yeast strain is not sufficient to make the claimed yeast strains because the skilled artisan would not be able to perform a repeatable process to obtain the claimed yeast, nor would the skilled artisan be apprised of what pre-existing yeast strains meet the claimed limitations.

First, random mutagenesis may result in a yeast strain that satisfies the test requirements. However, this is not an enabled method of making the yeast because the resulting yeast cannot be made again by a repeatable process, owing to the random nature by which it was originally obtained. Second, pre-existing yeast could meet the desired characteristics of the identification test, although it is unknown that the pre-existing yeast has the inherent property. That is because one of skill in the art could not consider the genetic properties of the yeast and determine

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whether it meets the requirements of the claimed invention. Thus the broad scope of the invention is not enabled because of the unpredictable nature of what yeast fit the limitations of the claimed yeast.

**State of the art.** The state of the art regarding baker's yeast strains is well known. Many hundreds of thousands of yeast strains exist in both industry settings and research facilities. The preponderance of these yeast strains are characterized with regard to their specific genetic backgrounds, and one of skill in the art could readily discern what functional characteristics are conferred upon the yeast as a result of specific genetic alterations. For example, the skilled artisan would be well aware that a deletion or other mutation of a gene involved in Nucleotide Excision Repair (such as Rad4, Rad23, Rad2, etc.) would result in a sensitivity of the strain to DNA damaging agents (for review, see Prakash *et al. Mutation Research* **451**: 13-24, 2000; see entire document; this document is provided to establish that genetic characterization results in the ability to predict phenotype); this is true as it regards any biological pathway in yeast. The skilled artisan would also understand from the state of the art that until a particular genetic characterization is performed, one could not reasonably predict how any particular strain will perform in a given assay. In the instant case, one of skill in the art would not be able to reasonably predict which yeast strains would have the desired characteristics set forth as limitations in the instant claims. Upon a review of the state of the art, the skilled artisan would understand that any given yeast requires some type of genetic characterization with regard to a desired characteristic before one can predictably make a yeast strain with the desired characteristic. Similarly, the skilled artisan would understand that a test to identify a yeast strain as having a particular performance in an assay would not result in the ability to make that same

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yeast in a predictable manner. Because the state of the art is silent as it regards the identification of genes which confer the desired characteristics set forth in the instantly claimed invention, the skilled artisan would have to turn to the instant specification in order to glean what yeast strains would meet the limitations of the instant claims.

**Number of working examples and Guidance provided by applicant.** The instant specification gives relatively little guidance as it regards the ability to make the claimed yeast. The specification appears to indicate that the particular deposited I-2421 and I-2422 yeast have the characteristics that are required to meet the limitations of the instant claims; however, there is no genetic characterization of these strains indicating what genetic manipulations result in the desired characteristics. Therefore, the skilled artisan would not be apprised as to how to make “similar” strains with the same characteristics. Furthermore, it appears that a complete deletion of the *PAD1* gene also confers the desired characteristics upon a given yeast strain (perhaps this is the mutation that appears in the I-2421 and I-2422 strains; it is unclear if this is so). It would be clear to the skilled artisan from the instant specification that strains deleted for the *PAD1* gene would also meet the limitations of the instant claims. However, the skilled artisan would not be able to discern what other yeast strains would meet the limitations of the instant claims from the instant specification. This is because there is no description of what other genes (besides a *PAD1* deletion) are responsible for conferring the desired characteristics upon a given yeast strain. The state of the art does not overcome this deficiency, as stated above. Therefore, the skilled artisan would only be able to make the I-2421 and I-2422 strains, and strains deleted for the *PAD1* gene as it relates to the instantly claimed invention.



**Unpredictability of the art and Amount of experimentation required.** The art is highly unpredictable. The skilled artisan cannot predictably make a strain that results in the desired characteristics. While it is true that the skilled artisan could obtain sample of the deposited yeast, or make a strain with a deletion in *PADI*, the skilled artisan would not know what other strains would meet the claimed limitations. For instance, would a strain mutated in *RAD2* also meet the claimed limitations? It is impossible to tell this from either the instant specification or the prior art; one can only be aware that the deletion of *PADI* has some effect on obtaining the desired characteristics. This same statement can be made for every individual gene in the yeast genome (approximately 6000), and can then be expanded for double and triple combinations of gene deletions or mutations; this is done with almost no guidance as to what individual or combinations of genes would give rise to the desired characteristics of a given yeast. Thus, a test to identify which yeast strains meet the desired limitations is little more than an invitation to empirical experimentation, or an invitation to find all of the possible genetic permutations that result in the claimed invention. This represents a huge amount of undue and unpredictable trial and error experimentation that must be performed in order to make the full scope of the claimed invention.

In conclusion, the full scope of the claimed invention is not enabled. The skilled artisan would understand from the specification that the deposited yeast strains I-2421 and I-2422, as well as a strain harboring a deletion in the *PADI* gene, are enabled within the scope of the instant claims. However, the skilled artisan would have no idea as to what other strains or genetic manipulations would result in the ability to make the full scope of the claimed invention. As a result, the indicated claims are not enabled for the full scope in which they are claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is necessitated by amendment.**

Claims 41-43 are directed to a process/method for the preparation of baker's yeast. However, there no steps set forth in the claimed method. In other words, the claims are directed to a method wherein there are no method steps. The claim is indefinite because the skilled artisan would not know what steps must be practiced in order to meet the limitations of the claims. Furthermore, the claim is impossible to search because it is unknown what steps make up the claimed process; therefore, it would be impossible to determine if a process in the prior art was anticipatory of the claim because it is unclear if said process would teach each and every limitation of the claimed process. It would appear that the respectively depending claims 44-46 set forth the proper method step required to practice the claimed method. It would be remedial to combine the limitations of the dependent claims into the rejected claims to obviate this particular rejection

Claims 27-31, 41-43 and 47-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "starting strain." It is unclear what the purpose of the "starting strain" is in the context of the claim. The skilled artisan would

not be apprised as to whether the “starting strain” was a strain that was being mutated to achieve the claimed strain, or if the “starting strain” was in fact the claimed strain. **This is a new rejection that is necessitated by amendment.**

Claims 27, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process steps that are required to obtain the control yeast. Applicant refers to this process by the incorporation of a reference (Reed *et al.*). This is an improper incorporation by reference because the method steps are required in order to practice the claimed invention. It is unclear what method steps that are set forth in this claim are required to practice the claimed invention without setting forth the method steps in the claim, therefore the indicated claims are indefinite. **This is a new rejection that is necessitated by amendment.**

Claims 28-31 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims recite the limitation whereby a yeast strain is “obtained by a process.” However, there are no method steps set forth in the claim relating to the process that is used to obtain these yeast strains. Therefore, it is impossible for the skilled artisan to ascertain what process must be performed in order to obtain the instantly claimed yeast. Alternatively, it is unclear if the claims are actually directed to the yeast strains, or the process by which the strains are obtained. In other words, if the claims are directed to the

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strains, and the method steps are not important (gleaned from their complete omission from the claims), it would appear that the method steps are irrelevant to the product because the claim is a product-by-process claim, where the steps would clearly not confer a structure-function characteristic on the claimed product (based on their unimportance). Similarly, if the claims are directed to the process of obtaining the yeast, the method steps should be clearly set forth and the preamble should be changed to clearly indicate the claims as being directed towards a method of obtaining yeast, and not the yeast themselves. **This is a new rejection that is necessitated by amendment.**

#### Maintained Rejections

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-37 ad 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection, although technically necessitated by amendment to the claims because all of the previously rejected claims have been cancelled, is essentially the same rejection set forth regarding claims 1-19, 23 and 24; thus, the rejection is maintained for the reasons set forth in the previous Office Action, and applied to newly added claims 26-53.**

The term "good general performances " in claims 26 and 37 is a relative term which renders the claim indefinite. The term "good general performances " is not defined by the claim,

the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, the skilled artisan would be unable to determine if a claim limitation is met because the skilled artisan would be unable to definitively ascertain if a particular yeast was considered to have a "good general performance," there being no definitive parameters set forth to indicate what a "good general performance" is.

The term "bad taste and off flavors" in claims 26 and 37 is a relative term which renders the claim indefinite. The term "bad taste and off flavors" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, the skilled artisan would be unable to determine if a claim limitation is met because the skilled artisan would be unable to definitively ascertain if a particular yeast was considered to produce a "bad taste and off flavors," there being no definitive parameters set forth to indicate what constitutes "bad taste and off flavors."

The term "similar" in claims 30, 33, 36-37 and 43 is a relative term which renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, the skilled artisan would not know if a particular strain was similar to the strains indicated in the claims because the skilled artisan would not know what characteristics would make the strains "similar," nor would

the skilled artisan be able to ascertain what level of similarity is required for a strain to be considered similar. Therefore would not be able to ascertain whether or not a particular strain met the limitations of the claim.

***Response to Arguments Concerning Claim Rejections - 35 USC § 112***

Applicant's arguments filed September 3, 2003 have been fully considered but they are not persuasive. The arguments consist of the following points:

1. The term "similar," although a relative term, is clearly defined as strain that share a common property. These properties are the ability to perform to certain standards in particular tests (see pages 17-18, the bridging paragraph, of applicant's arguments).
2. The term "good general performances" is clearly defined because it is general knowledge of one skilled in the baker's art. Such a performance can be evaluated "for example" by using fermentometer tests (see page 18, second and third full paragraphs, of applicant's arguments).
3. The term ""bad taste or off-flavors" is clearly defined from page 5, line 9 to page 6, line 25, where a test is disclosed to determine the production of "bad taste or off-flavors."

Applicant's arguments have been fully considered but are not convincing for the following reasons:

1. The term similar remains indefinite because it is a relative term. The skilled artisan could not reasonably ascertain how similar a strain must be to a reference strain in order to be considered "similar." The question of how well a strain performs in a test as a question of "similarity" (as provided in applicant's arguments) is now further addressed in the newly added enablement

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rejection. Briefly, the rejection indicates that the common properties among the I-2421 and I-2422 strains that must be maintained are unclear; therefore those properties are also unclear in the context of a “similar strain.” Furthermore, the desired properties of the reference strains (“good general performances” and “bad taste or off-flavors”) are themselves indefinite, and would therefore be indefinite in the context of “similar strains” as well.

2. An example of a test that can be performed *to determine* if a given strain has a particular performance is not a definition of “good general performances.” This is more completely addressed in the newly added enablement rejection where it is presented that a method *to identify* a strain is not a method *to make* a strain. Furthermore, this is still a relative term, as one artisan’s opinion of a “good performance” can be subjectively lower in standard than a second artisan’s, absent a clear definition of standards in the claim. In this instance, it is unclear which artisan’s opinion of a “good general performance” would be accurate, and applicable to the instant claim. Therefore, the skilled artisan cannot determine the metes and bounds of the term “good general performances.”

3. The term “bad taste and off-flavors” remains a subjective term, even in the context of the purported definition on pages 5 and 6 of the instant specification. The specification indicates on page 5, line 27 to page 6, line 3 that a jury determines the presence or absence of “bad taste and off-flavors.” This accentuates the subjectivity of the term because the composition of the jury will greatly influence the outcome of the test. For example, at a given time, a jury consisting of one group of people may decide that something gives “bad taste or off-flavors,” whereas a second jury will decide that it does not. In this instance, it is unclear which jury is correct in its

opinion. Therefore, the skilled artisan cannot determine the metes and bounds of the term "bad taste and off-flavors."

### ***Conclusion***

It is noted that the rejections set forth in the instant specification are either maintained for reasons set forth in the previous Office Action or are necessitated by amendment. However, this rejection is not being made FINAL because the rejections that are necessitated by amendment could have been applied to the previously pending claims.

### ***Allowable Subject Matter***


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.  
AU1636

  
JAMES KETTER  
PRIMARY EXAMINER